tubercular and influenza conditions; effective as a preventative for influenza and pneumonia; effective to stop coughs and as a treatment for coughs; effective as a distinct germicidal possessing antiseptic and prophylactic properties when used as directed; effective as a treatment in dry and persistent cough and to clear up cuptious or moist cough; effective as a treatment, remedy, and cure for hard, dry bronchial coughs, cuptious or moist coughs, hay fever, whooping cough, bronchial asthma, bronchitis, pneumonia, and influenza; effective as a relief for tubercular coughs and as a remedy to give instant relief and destroy the cause of bronchial coughs; and effective as a germ killer, when used as directed.

On September 21, 1932, the defendants each entered a plea of guilty to the information, and the court imposed fines totaling $50.

R. G. TUGWELL, *Acting Secretary of Agriculture.*

20371. Misbranding of Vapex. U.S. v. 11 Dozen Cartons of Vapex. Hearing on demurrer to claimant's amended special plea. Demurrer sustained. Decree of condemnation and destruction, with forfeiture provision for release under bond for relabeling. (F. & D no. 24768. I.S. no. 017180. S. no. 3120.)

This action involved the interstate shipment of a drug preparation, known as Vapex, which failed to bear on the package or label a statement of the quantity or proportion of alcohol contained in the article.

On May 15, 1930, the United States attorney for the District of Maryland, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for the district aforesaid a libel praying seizure and condemnation of 11 dozen cartons of Vapex, remaining in the original unbroken packages at Baltimore, Md., alleging that the article had been shipped in interstate commerce, on or about April 28, 1930, by E. Fougera & Co., Inc., from New York, N.Y., to Baltimore, Md., and charging misbranding in violation of the Food and Drugs Act.

Analysis of a sample of the article by this Department showed that it consisted essentially of volatile oils, including lavender oil and menthol, and alcohol (67 percent by volume).

It was alleged in the libel that the article was misbranded in that the packages containing the article failed to bear a statement on the label of the quantity or proportion of alcohol contained therein.

On June 14, 1930, E. Fougera & Co. Inc., New York, N.Y., interposed a claim for the property and filed its answer praying dismissal of the libel. Subsequently claimant's answer was withdrawn and a special plea was entered. On December 22, 1931, the special plea having been withdrawn, claimant filed an amended special plea, to which the Government demurred.

The case was set for hearing on May 17, 1932, on briefs submitted by the Government and the claimant, no oral argument being made. On June 7, 1932, the court handed down the following opinion sustaining the Government's demurrer: (Chesnut, *D.J.*):

"In this proceeding at law (by the applicable statute called a libel) the Government seeks to condemn a quantity of 'Vapex', shipped in interstate commerce, on the ground that it is misbranded under section 8, paragraph 2, of the Food and Drugs Act of Congress (U.S.C., title 21, sec. 10).

"The misbranding is alleged to result from the failure of the package 'to bear a statement on the label of the quantity or proportion of any alcohol * * *, or any derivative or preparation of any such substances contained therein.'

"By its second amended plea filed February 12, 1932, the claimant, E. Fougera & Co., Inc., admits all the allegations of fact contained in the libel but, in opposition to the claimed condemnation, sets up the following contentions, in substance: (1) that the 'Vapex' as shown by the labels on the packages is 'a pure inhalant generally indicated in the treatment of head colds'; (2) that the directions for using it are to place a drop or two in the center of a folded handkerchief and inhale the vapor therefrom; (3) that the alcohol contained in the article 'has no office or property therein other than as a diluent or solvent of the essential oils contained therein.' From these facts in the plea the legal conclusions are drawn that (a) Vapex is not a drug within the meaning of the act; (b) the act properly construed does not apply to Vapex; (c) that if construed to apply to Vapex the act is unconstitutional in the absence 'of a showing that the alcoholic content of said article renders the same noxious or harmful to the public health.'

"The Government challenges the sufficiency of the plea to establish these conclusions.

"After a study of the excellent briefs submitted by counsel, I have reached the conclusion that the demurrer should be sustained for the following reasons:

"The term 'drug' as used in the act is defined to include 'all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals.' U.S. Code, title 21, sec. 7. The definition so clearly includes the substance 'Vapex' (as it is described in claimant's plea) that discussion seems unnecessary. The labels on the bottles as quoted in the plea state that the inhalation of the vapor from a drop of Vapex on a handkerchief is effective to relieve a head cold instantly and that its use will stop a cold at the start. It is further described as a new method of treatment for colds. The labels also assert that its use is both curative and preventative, and that breathing the vapor is inimical to the germs of common colds. It is clearly, therefore, a substance 'intended to be used for the cure, mitigation, or prevention of disease,' unless it were denied, as it is not, and as I think it could not be, that a head or common cold is a disease. See U.S. *v.* 23 7/12 Dozen Bottles, 44 F. (2d) 831 (D.C.Conn.).

"The more substantial contention of the claimant is that Vapex, by reason of its nature and use, is without the substantial intent although within the literal content of the wording of the act. It is urged that the purpose of Congress in requiring preparations containing alcohol to state the percentage thereof on the label was to prevent the user of medicine from unconsciously acquiring a taste for alcohol disguised as medicine; and a comparative reference is made to the section of the same law relating to food preparations which omits any requirement that food products containing alcohol (often contained therein, it is said, as preservatives) must state upon their labels the quantity contained. It is argued for the claimant that a medicine or drug used only for inhalation and not otherwise for internal use could not reasonably be within the substantial intent of Congress in requiring the percentage of alcohol to be stated on its label. The substance of this contention is that inhaling vapor from alcohol is harmless and not habit-forming and therefore could not have been within the intent of the act as to misbranding. But this contention is only a re-statement of the claimant's first contention which was that an inhalant is not a drug which, as above noted, is I think not tenable. And if an inhalant is covered by the definition of a drug, then the misbranding section is expressly applicable to it. The statute makes no exception and I do not think the court is at liberty to read an exception into the act even though if the matter had been brought specially to the attention of the Legislature it might have done so in the original enactment. See U.S. *v.* 65 Casks, 170 F. 449 (D.C.N.D.W.Va.), affirmed (C.C.A.) 175 F. 1022.

"It is a well-settled principle of statutory construction that the intention of the Legislature is to be sought primarily in the language used, and where this expresses an intention reasonably intelligible and plain, it must be accepted by the courts without modification by resort to construction or conjecture. Thompson *v.* U.S., 246 U.S. 547, 38 S.Ct. 349, 62 L.Ed. 876.

"In support of its contention the claimant relies upon the cases of U.S. *v.* Antikamnia Chemical Co., 231 U.S. 654, 34 S.Ct. 222, 58 L.Ed. 419; Hall-Baker Grain Co. *v.* U.S., 198 F. 614 (C.C.A. 8th); McDermott *v.* Wisconsin, 228 U.S. 115, 33 S.Ct. 431, 57 L.Ed. 754, 47 L.R.A. (N.S.) 984, Ann. Cas. 1915A, 39. But I find nothing in these cases which, in my opinion, gives any substantial support to the contention. And it may also be said that the question as to whether the inhaling of alcohol is habit-forming and consequently harmful is hardly raised by the pleadings. In any event it is hardly within the scope of judicial knowledge that alcohol as an inhalant is necessarily harmless, and I do not feel warranted in determining that Congress could not have intended that preparations for inhalation only should be required to bear a statement of alcoholic content on the label. Assuming that the matter is debatable, it seems entirely clear that Congress was entitled to exercise its own judgment, not to be superseded by the verdict of a jury or the personal opinion of a judge. Hebe Co. *v.* Shaw, 248 U.S. 297, 303, 39 S.Ct. 125, 63 L.Ed. 255.

"Finally, it is contended for the claimant that if 'Vapex' is within the language of the act as properly construed, it is nevertheless without the power

of Congress to prohibit its transportation in interstate commerce, because, as directed to be used, it is a harmless substance in no way detrimental to the public health. Emphasis is laid on the wording of the opinions in many of the cases in the Supreme Court dealing with the Food and Drugs Act to the effect that the primary purpose of Congress was to prevent injury to the public health and that the prohibition was only against impure food and drugs. See Hipolite Egg Co. *v.* U.S., 220 U.S. 45, 31 S.Ct. 364, 55 L.Ed. 364; Seven Cases Eckman's Alterative *v.* U.S., 239 U.S. 510, 36 S.Ct. 190, 60 L.Ed. 411, L.R.A. 1916D, 164; Hoke *v.* U.S., 227 U.S. 308, 322, 33 S.Ct. 281, 57 L.Ed. 523, 43 L.R.A. (N.S.) 906, Ann. Cas. 1913E, 905; McDermott *v.* State of Wisconsin, 228 U.S. 115, 33 S.Ct. 431, 57 L.Ed. 523, 754, 47 L.R.A. (N.S.) 984, Ann. Cas. 1915A, 39. And importantly reference is made to the Child Labor Case (Hammer *v.* Dagenhart), 247 U.S. 251, 38 S.Ct. 529, 62 L.Ed. 1101, 3 A.L.R. 649, Ann. Cas. 1918E, 724, where the Supreme Court held invalid an act of Congress which prohibited interstate commerce in articles manufactured by child labor under certain conditions. But in that case the articles themselves were the ordinary and usual subjects of commerce, entirely harmless in themselves, and the aim of the statute was thought to be to equalize labor conditions in the several States rather than protect the public against the use of harmful articles. For this reason the legislation was held beyond the powers of Congress under the interstate commerce clause of the Constitution.

"It is true that the Food and Drugs Act does forbid interstate commerce in impure food and drugs, but the scope of the act is not limited to that subject alone. It also includes the regulation of interstate commerce in drugs and food that are not impure and not of themselves harmful, including the requirement that the articles shall not be misbranded. In the judgment of Congress consumers of articles, harmless in themselves when used as directed, are entitled nevertheless to be advised of the existence in the articles of ingredients belonging to classes of articles which were regarded as potentially harmful of themselves, even though contained in harmless quantities in the articles as designed for consumption. To this end Congress provided that the package must contain a statement on the labels of the quantity of alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate or acetanilide, or any derivative or preparation of any such substance contained therein. Such substances classified as 'narcotics' are obviously harmful when used in excessive quantities. Within the proscribed class is alcohol. Drugs containing such narcotics when properly labeled are not forbidden the facilities of interstate commerce. The effect of the act with regard thereto is to regulate rather than prohibit and it can no longer be doubted that such regulation is within the power of Congress. U.S. *v.* Antikamnia Chem. Co., 231 U.S. 654, 34 S.Ct. 222, 58 L.Ed. 419; Glaser, Kohn & Co. *v.* U.S., 224 F. 84, 89 (C.C.A. 7th). As Vapex is a drug containing alcohol, it comes clearly within the prescribed class even though the article as designed and directed to be used by the consumer is itself innocent and innocuous. The controlling principle applicable to the case is to be found in Purity Extract Co. *v.* Lynch, 226 U.S. 192, 201, 33 S.Ct. 44, 46, 57 L.Ed. 184, where Mr. Justice Hughes, speaking for the Supreme Court, said: 'It does not follow that because a transaction, separately considered, is innocuous, it may not be included in a prohibition the scope of which is regarded as essential in the legislative judgment to accomplish a purpose within the admitted power of the Government.' And again at page 204 of 226 U.S., 33 S.Ct. 44, 47, he continued as follows: 'The statute establishes its own category. The question in this court is whether the legislature had power to establish it. The existence of this power, as the authorities we have cited abundantly demonstrate, is not to be denied simply because some innocent articles or transactions may be found within the proscribed class. The inquiry must be whether, considering the end in view, the statute passes the bounds of reason and assumes the character of a merely arbitrary fiat.'

"The question in that case was whether a substance called 'Poinsettia', itself entirely innocuous but containing an ingredient forbidden by the statute of Mississippi, was prohibited by the act which, as construed by the State court, forbade the sale of all malt liquors. The court held that the article in question was within the act.

"The same principle has been subsequently applied by the Supreme Court to other analogous situations. As in Hebe Co. *v.* Shaw, 248 U.S. 297, 39 S.Ct. 125, 126, 63 L.Ed. 255, a similar situation, Mr. Justice Holmes, speaking for the court, said: 'The power of the Legislature" is not to be denied simply because

some innocent articles of transactions may be found within the proscribed class. The inquiry must be whether, considering the end in view, the statute passes the bounds of reason and assumes the character of a merely arbitrary fiat." Purity Extract & Tonic Co. *v.* Lynch, 226 U.S. 192, 204, 33 S.Ct. 44, 47 (57 L.Ed. 184). If the character or effect of the article as intended to be used "be debatable, the Legislature is entitled to its own judgment, and that judgment is not to be superseded by the verdict of a jury", or, we may add, by the personal opinion of judges, "upon the issue which the Legislature has decided." Price *v.* Illinois, 238 U.S. 446, 452, 35 S.Ct. 892 894, (59 L.Ed. 1400); Rast *v.* Van Deman & Lewis Co., 240 U.S. 342, 351, 357, 36 S.Ct. 370, 60 L.Ed. 679, L.R.A. 1917A, 421 Ann. Cas. 1917B, 455. The answer to the inquiry is that the provisions are of a kind familiar to legislation and often sustained and that it is impossible for this court to say that they might not be believed to be necessary in order to accomplish the desired ends.'

"And the same principle was again applied by the Supreme Court in the cases of Pierce Oil Corporation *v.* City of Hope, 248 U.S. 498, 500, 39 S.Ct. 172, 63 L.Ed. 381, and Euclid *v.* Ambler Co., 272 U.S. 365, 388, 47 S.Ct. 114, 71 L.Ed. 303, 54 A.L.R. 1016.

"If we assume that the inhalation of Vapex is innocuous, nevertheless it is within the category of articles which, by the act, are required to contain a declaration on the label of the alcoholic content. And it cannot be said at this time that a statute which merely regulates interstate commerce in drugs containing alcohol, passes the bounds of reason or assumes the character of an arbitrary fiat. It is, therefore, not permissible for the court to make an exception where Congress has made none, and thus to withdraw from the operation of the statute an article which, even though harmless itself, is otherwise within the proscribed class.

"The demurrer is, therefore, sustained."

On September 12, 1932, judgment of condemnation and forfeiture was entered and it was ordered by the court that the product be destroyed. The decree provided, however, that the said product might be released to the claimant upon payment of costs and the execution of a bond in the sum of $200, conditioned that it be relabeled to show the true alcohol content.

R. G. TUGWELL, *Acting Secretary of Agriculture.*

20372. Misbranding of Miller's Anti-Mole. U.S. v. 18 Bottles of Miller's Anti-Mole. Product adjudged misbranded and ordered destroyed. (F. & D. no. 28438. Sample no. 6105-A.)

Examination of the drug preparation involved in this action disclosed that the article contained no ingredient or combination of ingredients capable of producing certain curative and therapeutic effects claimed in the labeling.

On July 1, 1932, the United States attorney for the Western District of Missouri, acting upon a report by the Secretary of Agriculture, filed in the District Court of the United States for the district aforesaid a libel praying seizure and condemnation of 18 bottles of Miller's Anti-Mole, remaining in the original unbroken packages at Kansas City, Mo., alleging that the article had been shipped in interstate commerce on or about June 9, 1932, by the Miller Manufacturing Co., Lincoln, Nebr., to Kansas City, Mo., and charging misbranding in violation of the Food and Drugs Act as amended.

Analysis of a sample of the article by this Department showed that it consisted essentially of nitric acid (65 percent), acetic acid (10 percent), and water (25 percent).

It was alleged in the libel that the article was misbranded in that the following statements appearing on the labeling were false and fraudulent: (Label around wooden tube) "Anti-Mole for the permanent removal of moles, * * * and all similar skin blemishes"; (circular "Anti-mole * * * is Guaranteed to Permanently remove Moles, * * * and all healthy protuberances protruding above the skin, * * * For a small mole insert the point of a common hard-wood toothpick into the liquid, with a downward stroke shake off the drop of liquid and apply with the pick just moistened a little, thus preventing the liquid from spreading to the surrounding skin. For a very small mole, or dark skin spot, a very slight application of the remedy well worked in will be sufficient. For a very large protruding mole, say the size of a large pea, more of the remedy is required. Apply Anti-Mole to the surface of the mole, pick gently with the toothpick while applying. When the very small mole turns a light color you have used sufficient to remove it; a large mole, use enough to turn it brown; About 2 hours